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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,025	10/24/2003	Suzanne M. Torontali	HO-P02882US0 (9394L)	1757

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EXAMINER	
SKIBINSKY, ANNA	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,025	TORONTALI ET AL.	
	Examiner	Art Unit	
	Anna Skibinsky	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4 pages*. 3/28/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Election/Restriction

1. Applicant's election with traverse of Group I in the reply filed on 7/18/2006 is acknowledged. The traversal is on the ground(s) that both Groups I and II are classified in the same class and subclass, i.e. 436/6. Applicants also argue that there is no burden of search. This is not found persuasive because each class and subclass contains thousands of distinct inventions that are categorized together but nevertheless are different. Groups I and II are a method for amplifying a signal and method of optimizing a hybridization assay which are different methods and entail a search burden if searched together. Restriction is made based on the distinctness of the invention as well as burden of search.

2. The requirement is still deemed proper and is therefore made FINAL.

3. Claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/18/2006.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (US Pub 2001/0041335) as applied to claims 1-18, and further in view of Mirkin et al. (US Patent 6,582,921).

3. Claim 1 recites a microsphere linked to a pre-optimized oligonucleotide hybridizing a labeled target polynucleotide to the oligonucleotide to form an oligonucleotide/target complex. The complex comprises a detectable signal through the binding of a receptor to the label. Furthermore, a labeled ligand is provided for the receptor wherein the ligand binds to the receptor and the signal is detected.

4. Goldberg et al. teach the target polynucleotide that is labeled with a ligand and a receptor (Abstract, lines 4-13) as in claim 1, steps (b) and (c). The ligand can be contacted with a labeled receptor, thus providing a labeled ligand for the receptor as in claim 1, steps (c). The oligonucleotide can hybridize to a DNA sequence with the reverse compliment sequence to form an oligonucleotide/target polynucleotide complex

(col. 6, line 67 to col. 7, line 3). The method of the invention is to detect target molecules through a detectable signal (Abstract, lines 1-4 and 22-26).

5. Goldberg et al. do not teach a microsphere linked to a pre-optimized oligonucleotide as required by claim 1, step (a). However, Mirken et al. teach nanoparticle-oligonucleotide conjugates (Abstract) wherein the oligonucleotide has a sequence complementary to a sequence of nucleic acid (col. 2, lines 29-32) and where the nanoparticle to which the oligonucleotide is attached is a micorsphere (col. 6, lines 48-50).

6. Claims 2, 3, 6 and 7 recite a pre-optimized oligonucleotide that is selected with an algorithm wherein the one perfect match pre-optimized oligonucleotide has an acceptable measure of correlation with a standard gene expression value, or based on mismatched criteria.

7. Mirkin et al. teach the detection of genes and gene therapy (col. 21, line 51 to col. 22, line 7) where the hybridized probe oligonucleotides are detectable by visualization of a spot (col. 23, line 34 to col. 24, line 24) which is a standard gene expression value as in claim 3, step (a). Oligonucleotides may also be selected using mismatches between the probe and the polynucleotide (col. 24, lines 26-39), as in claim 3, step (b).

8. Claims 4 and 5 recite providing a sample of target RNA polynucleotides for more than one gene, subjecting the sample to an array of oligonucleotides that hybridize to more than one different RNA polynucleotide and provide a detectable hybridization finger print for more than one gene that can be identified.

9. Mirkin et al. teaches a gene chip assay (Example 19) where different oligonucleotides (col. 84, lines 47-50) hybridize to different sequences (col. 85, lines 61-63), differentiated by a nucleotide at position "N" (Figure 32). The method of the invention can also be applied to RNA and a plurality of genes associated with cancer (col. 21, line 51 to col. 22, line 7). The detection of the hybridization of oligonucleotides is fingerprinted by a visible spot (Example 19; and col. 23, line 42 to col. 24, line 25).

10. Claims 9 and 10 recite a ligand that comprises an antibody and a label that is a fluorescent label, chemical, enzyme or gold label. Goldberg et al. teach a ligands that include antibodies (col. 10, lines 53-67) and labels at include fluorescent, gold, or enzymatic labels (col. 12, lines 18-23).

11. Claim 8 recites a concentration from about 1 to 10 micrograms of the target polynucleotide.

12. Mirkin et al. teach a solution of 10 microliters of a 1 nanomolar solution of target.

13. Claim 11 recites the label of the target polynucleotide and the ligand are identical. Goldberg et al. teach that the label may be provided on the amplification reagent, or the binding ligand (col. 12, lines 18-23). Once the polynucleotide and ligand complex if formed (Abstract), the label is shared by both polynucleotide and ligand and is thus the same as required by claim 11.

14. Claims 12 recites that the microspheres are comprised in a plurality of microspheres and the target polynucleotides are comprised in a plurality of RNA polynucleotides.

15. Mirkin et al. teach a plurality of microspheres having oligonucleotides attached where the oligonucleotide sequences have a sequence complimentary to the sequence of the nucleic acid and are labeled with a fluorescent molecule (col. 6, lines 48-52). Furthermore, the nanoparticle microspheres and polynucleotides can form larger microsphere complexes (Figure 18; and col. 16, line 66 to col. 17, line 4). The method of the invention provides a way of detecting RNA, which is the target polynucleotide (col. 21, lines 51-61).

16. Claim 13 recites the plurality of RNA is comprised in a mRNA sample and a method for providing mRNA expression profiling information is further defined.

17. Mirkin et al. teach that the detected RNA include mRNA (col. 21, lines 51-61) and that nucleic acids may be detected in samples of solutions with PCR containing components (col. 22, lines 19-32).

18. Claims 14-18 recites at least one oligonucleotide that is different from the other oligonucleotides on the microsphere and where the microsphere comprises more than one non-identicle pre-optimized oligonucleotide having a sequence complementary to the same RNA polynucleotice.

19. Mirkin et al. teach microspheres to which different oligonucleotides may be attached (a, b, c, d, e, etc) where each microsphere may have more than one oligonucleotide, as shown in Figure 17(a)-(c) (col. 16, lines 57-65). The oligonucleotides bind to the same polynucleotide as shown, to specific complementary regions along the same polynucleotide.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have implemented the labeld polynucleotide sequences with receptors of Goldberg et al. with the binding of oligonucleotides attached to microspheres as taught by Mirkin et al. One of skill in the art would have been motivated to use the oligonucleotides bound to micorspheres as taught by Mirkin et al. to bind to the labled polynucleotides of Goldberg et al. because both Mirkin et al. and Goldberg et al. teach a oligonucleotide/target complexes immobilized on a surface, where the surface is interchangeable from a typical array substrate to a bead or nanoparticle (Goldberg et al., col. 6, line 66 to col. 7, line 3 and Mirkin et al. Abstract). Goldberg et al. and Mirkin et al. both teach a hybridization detection method where oligonucleotides bind to polynucleotides, but Goldberg et al. teaches a microsphere instead of a typical array attached to the nucleic acid sequence, thus one of skill in the art would have had a reasonable expectation of success at producing the oligonucleotide-microsphere/labled-target complex as recited in the claims as both references teach polynucleotides attached to surface substrates.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anna Skibinsky, PhD